



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3692]

Evaluating the Pressor Effects of Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled “Evaluating the Pressor Effects of Drugs.” This public workshop is convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA. The purpose of this public workshop is to bring the stakeholder community together to discuss the premarketing assessment of a drug’s effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Agency staff will present findings related to the use of ambulatory blood pressure monitoring to assess treatment effects.

DATES: The public workshop will be held on Monday, February 4, 2019 from 8:30 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at 1777 F Street NW, Washington, DC 20006.

For additional travel and hotel information, please refer to the following website:

<https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>.

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4166, Silver Spring, MD 20903, 301-796-2240, email: Norman.Stockbridge@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding FDA's assessment of the pressor effects of drugs. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Following FDA's announcement in the *Federal Register* of the availability of a draft guidance for industry entitled "Assessment of Pressor Effects of Drugs" (May 31, 2018, 83 FR 25013), FDA is convening this public meeting in collaboration with the Duke-Margolis Center for Health Policy to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

Topics for discussion during this meeting include:

- Risk associated with blood pressure change
- Aspects and FDA analyses related to ambulatory blood pressure monitoring
- Evaluating a drug's effect on blood pressure and understanding the optimal regulatory approach to assigning risk

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website:
<https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood->

pressure-monitoring-studies. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by Thursday, January 31, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Duke-Margolis will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (202-791-9561, email: sarah.supsiri@duke.edu) no later than November 29, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting <https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>. The live webcast will also be available at the website above on the day of the event without preregistration. Archived video footage will be available at the Duke-Margolis website following the workshop.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website <https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>.

Dated: November 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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